UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/419,901	10/18/1999	JENNIFER E. VAN EYK	1997-023-04U	2043

26259 7590 03/09/2005

LICATLA & TYRRELL P.C.
66 E. MAIN STREET
MARLTON, NJ 08053

EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/419,901	Applicant(s) VAN EYK ET AL.	
	Examiner Lisa V. Cook	Art Unit 1641	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 January 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See attached*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-7,15-28,31,34,35 and 37-41*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attached.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
03/07/05

Lisa V Cook
3/5/05

ADVISORY ACTION

Amendment Entry

1. The amendment filed 13 January 2005 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered because: The amendment changes the scope of the method. The amended method of claim 1 requires the presence of a myofilament protein modification product, which is a chemical adduct of a myofilament protein. Previously, the method of claim 1 read on the presence or absence of a protein modification product. The protein modification product was previously not required to be present and did not have to be a chemical adduct of a myofilament protein. Claim 1 is drawn to any and all post-translational chemical adduct myofilament protein modification products. The newly configured method of the amendment filed 1/13/05 would require additional search and considerations. Accordingly, the amendment was not entered.

2. Objections and/or rejections of record not reiterated below have been withdrawn.

OBJECTIONS WITHDRAWN

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the Examiner on form PTO-892 or Applicant on form PTO-1449 has cited the references they have not been considered.

4. The information disclosure filed 1/21/04 has been considered as to the merits before Final Action. Specifically, Canadian patent #2,243,372 has been considered.

Response to Arguments

Applicants contend that the listing of references in the specification was not meant to serve as an IDS. This argument has been considered and the objection is withdrawn.

Declaration

5. The Declaration by Jennifer Van Eyk filed 23 December 2003 has been entered and considered but does not overcome the rejection because co-pending application number 09/115,589 has been included in a provisional rejection under the judicially created doctrine of obviousness-type double patenting (ODP). The ODP rejection can only be overcome with a Terminal Disclaimer not a Declaration.

REJECTIONS MAINTAINED

Double Patenting

6. Double patenting obviousness-type rejection:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees.

See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-7, 15-28, 31, and 34-35, and 37-41 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 09/115,589. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are directed to the assessment of muscle damage in a subject via the detection of myofilament protein modification products. The instant claims require that one of the products be a chemical adduct of a myofilament protein. This invention is encompassed in the claims of application number 09/115,589 wherein the claims read on any myofilament protein modification product (including chemical adducts).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

The rejection will be held in abeyance until one of the applications is allowed. If at that time the obviousness-type double patenting issue still exists, Applicants will file the appropriate terminal disclaimer(s). Accordingly the rejection is maintained.

With respect to the art rejection presented below: The disclosure merely teaches the detection of TnI as it relates to muscle damage. The examiner takes TnI to be a protein meeting the limitations of a myofilament protein modification product being a chemical adduct of a myofilament protein. See disclosure page 1-lines 17-22, page 4-lines 5-8, page 30, and page 50. Accordingly in order to promote compact prosecution the following art rejection is applied.

Affidavit Under 37 CFR 1.131

8. The affidavit filed on 13 January 2005 under 37 CFR 1.131 has been considered but is ineffective to overcome the Van Eyk et al. (US patent #6,248,549) reference because applicant must further show that he or she made the invention upon which the relevant disclosure in the patent, application publication, or other publication is based. In re Mathews, 408 F.2d 1393,161 USPQ 276 (CCPA 1969); See MPEP 715.01(c)

II. >< DERIVATION

When the unclaimed subject matter of a patent, application publication, or other publication is applicant's own invention, a rejection>, which is not a statutory bar,< on that patent or publication may be removed by submission of evidence establishing the fact that the patentee, applicant of the published application, or author derived his or her knowledge of the relevant subject matter from applicant. Moreover applicant must further show that he or she made the invention upon which the relevant disclosure in the patent, application publication, or other publication is based. In re Mathews, 408 F.2d 1393, 161 USPQ 276 (CCPA 1969);

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 1, 15, and 16 remain rejected under 35 U.S.C. 102(b) as being anticipated by Wicks et al. (W0 94/27156).

Wicks et al. measure troponin I in a complex sandwich assay having immobilized solid phases for the purpose of assaying irreversible cardiac damage from biological samples such as blood. Specifically two binding partners are utilized, one capable of binding to troponin I and one binding partner specific for the C subunit of the troponin complex. (pages 2-5).

The test provides rapid and specific measurement of troponin I and is useful in confirming the diagnosis of myocardial damage.

Response to Arguments

Applicant contends that Wicks et al. do not teach the detection of chemical adducts as defined in the specification on page 14. This argument was carefully considered, but not found persuasive because the rejected claims under 102(b) above do not require the measurement of the chemical adduct. The claim reads on instances wherein the chemical adduct is "absent". The only required detection is a myofilament protein modification product. TnI meets this requirement as supported by Applicants disclosure on page 19 beginning at line 3, for example. Accordingly the rejection is maintained.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The patent of Van Eyke et al. was employed as prior art because priority was not claimed to the patented invention. The patent also contains a different inventive entity.

I. Claims 2-7, 17-28, 31, 33-35, and 37-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over being unpatentable over Wicks et al. (W0 94/27156) in view of Wicks et al. (US patent #5,834,220) and in further view of Van Eyk et al. (US patent #6,248,549).

Wicks et al. (W0 94/27156) is set forth above.

Wicks et al. (W0 94/27156) differs from the instant invention in not teaching an assessment of muscle damage employing the measurement of two different myofilament protein modification products.

However, Wicks et al. teach method for assaying for cardiac troponin I along with troponoin C. See abstract. The process and test system provide rapid and specific measurements of troponin I and is highly suitable for confirming the diagnosis of myocardial damage (reading on muscle damage).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to measure two different myofilament product degradation products (troponin I and troponin C) in muscle damage as taught by Wicks et al. in the method of Wicks et al. (W0 94/27156) involving troponin I analysis because Wicks et al. taught that Troponin I is one of three subunits of the troponin complex.

The other two subunits (designated T and C) are also immobilized on the thin myofilaments along with troponin I in both cardiac and skeletal muscle tissue. Column 1., lines 23-40. The utility of both troponin I and troponin C allowed for further distinction between cardiac muscle damage or skeletal muscles damage. See column 2, lines 37-49.

One having ordinary skill in the art would have been motivated to do this to acquire the enhanced sensitivity and ability to reduce false positives while providing more data sets for analysis, wherein accurate and precise detection is available.

Please see Wicks et al. (W0 94/27156) in view of Wicks et al. as set forth above.

Wicks et al. (W0 94/27156) in view of Wicks et al. differ from the instant invention in not teaching an assessment of muscle damage employing two different myofilament protein modification products from different proteins involving phosphorylation.

However, Van Eyk et al. teach method for assaying for muscle damage (contractile state). Including heart failure and myocardial stunning. See abstract. In one embodiment PAK kinase activity is assessed by measuring the phosphoryaltion of two different proteins (troponin I and calponin for example) see column 3, lines 30-39 and claim 4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to measure two different myofilament product degradation products from different protein with respect to their phosphorylation states (troponin I and Calponin) in muscle damage as taught by Van Eyk et al. in the method of Wicks et al. (W0 94/27156) in view of Wicks et al. to detect troponin I analysis because Van Eyk et al. taught that such method configurations allowed for the assessment of compositions in a screening format for their effect on PAK kinase activity or expression with respect to muscle disorders. See column 3, lines 1-39.

Response to Arguments

Applicant contends that Wicks does not teach methods for detecting chemical adducts or the relationship of chemical adducts to muscle damage. This argument was carefully considered but not found persuasive because the claims prior to the amendment filed 1/13/05 did not require the detection of chemical adducts. The claims merely read on the presence or absence of a myofilament protein modification product. TnI is a myofilament protein as supported by the disclosure on page 14 lines 5-9. Wicks et al. teach the determination of TnI in muscle damage. See W0 94/27156, accordingly the rejection is maintained.

With respect to the detection of chemical adducts, Wick et al. (W0 94/27156) are cited in combination with Wicks et al. (US patent #5,834,220) and in further view of Van Eyk et al. (US patent #6,248,549) under obviousness. A deficiency in a reference is not overcome by pointing out that a reference lacks a teaching for which other references are relied. In re Lyons, 364 F.2d 1005, 150 USPQ 741, 746 (CCPA 1966).

The affidavit filed on 13 January 2005 under 37 CFR 1.131 has been considered but is ineffective to overcome the Van Eyk et al. (US patent #6,248,549) reference because applicant must further show that he or she made the invention upon which the relevant disclosure in the patent, application publication, or other publication is based. In re Mathews, 408 F.2d 1393,161 USPQ 276 (CCPA 1969); See MPEP 715.01(c)

II. >< DERIVATION

When the unclaimed subject matter of a patent, application publication, or other publication is applicant's own invention, a rejection>, which is not a statutory bar,< on that patent or publication may be removed by submission of evidence establishing the fact that the patentee, applicant of the published application, or author derived his or her knowledge of the relevant subject matter from applicant. Moreover applicant must further show that he or she made the invention upon which the relevant disclosure in the patent, application publication, or other publication is based. In re Mathews, 408 F.2d 1393, 161 USPQ 276 (CCPA 1969);

11. For reasons aforementioned, no claims are allowed.

12. Accordingly, **THIS ACTION REMAINS FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

13. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Takahashi et al. (W0 96/10078) disclose methods for detecting myosin light chain 1 (MLC-1) as an indication of cardiac damage. The assay is conducted in biological sample like blood.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Lisa V. Cook
Patent Examiner
Art Unit 1641
Remsen 3C-59
(571) 272-0816